IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of.:			
	Daphne ATLAS et al	Confirmation No.:	9326
Serial No.:	10/522,766		
Filed:	February 27, 2006	Group Art Unit:	1614
For:	TREATMENT OF MULTIPLE SCLEROSIS WITH BRAIN TARGETED ANTI-OXIDANT COMPOUNDS	Attorney Docket:	**29287**
Examiner:	FINN Meghan R.		

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 U.S.C. SECTION 1.131

Sir:

I, Daphne Atlas, declare as follows:

1) I am the Daphne Atlas who is an inventor named in the above-identified subject invention.

2) I am also a professor of chemistry. One of my specialties for the last [15] years is antioxidant chemical compounds, especially in the area of central nervous system diseases, such as MS. Accordingly, I am very familiar with the literature on this subject.

2) I understand that the claims are rejected as allegedly unpatentable over WO 98/29375 ("Atlas") in view of US 6,303,139 ("Passi") and in further view of Delack et al. (US 2003/0113309 A1). In making this rejection, a number of statements were made in the Office Action which I would like to address.

I. The proven success of other compounds in treating MS

A. Salen-metal complex compounds

3) The current Office Action states that Malfroy-Camine et al. (US Pat. No. 6,589,948) provides examples of other antioxidant compounds that are indicated for treating MS. Specifically, column 4, lines 26-46 of Malfroy-Camine cites the class of antioxidant salen-metal complex compounds for treating MS, as well as many other CNS diseases.

4) Malfroy-Camine provides no data whatsoever that shows that any species of this class of compounds can treat any CNS disease, much less MS. Moreover, it has been almost ten years since Malfroy-Camine was filed, and over seven years since this patent issued. I am aware of no publication that shows that any species of this class of compounds can treat MS.

B. Vitamins C and E

5) Previously, I cited an article showing that, while vitamins C and E were thought to help prevent the onset of MS, the data proved otherwise. In response, the current Action suggests that while these vitamins may not prevent MS, they could possibly treat MS.

6) There is absolutely no data showing that either of these vitamins can treat MS. Indeed, while it was originally speculated that these vitamins may help in preventing MS, I am aware of no such speculation as to either of them being able to treat MS.

7) I cited this article merely to show that, when it comes to antioxidant drug candidates for CNS diseases, especially MS, the skilled artisan would be very skeptical. Such skepticism would apply whether a given drug candidate was thought to treat or prevent MS.

II. The level of involvement of oxidative stress

8) The Office Action alleges that because oxidative stress is significantly involved in the pathogenesis of MS, it would be obvious to treat MS with an antioxidant compound such as compound J.

9) I do not take issue with the fact that oxidative stress may be a significant contributor towards the onset or progression of MS. But despite the significant role oxidative stress might play, the track record of antioxidants to successfully treat MS has been scanty at best. And, as discussed above, the disclosure of Malfroy-Camine regarding salen-metal complex compounds for treating MS amounts to nothing more than baseless speculation. Given this track record, regardless of whether oxidative stress plays a significant role in the pathogenesis of MS, at the time of my invention it would not have been obvious that compound J, or any other antioxidant drug candidate, would successfully treat MS.

III. Regarding the table provided

10) Previously, I provided a table of known drugs that treat MS. The point of the table was to show that out of all the known drugs for treating MS, only one drug is an antioxidant, although many, many antioxidant drugs are known. This clearly shows to me that a given antioxidant, such as compound J, is not obvious unless and until actual results are shown.

11) The Action further alleges that there is no reason to believe this list is comprehensive or that it represents all the treatments known in the art, but rather may be limited to only those which have already been approved by the FDA. To the best of my knowledge, this is a comprehensive list. In other words, as of the date of my invention (2004) and even today (2010), I am aware of no other antioxidant compounds that have been shown to successfully treat MS.

IV. Regarding other CNS diseases

12) The Office Action argues that the role oxidative stress may play in other CNS diseases is not relevant regarding whether it would be obvious to treat MS with a particular antioxidant, such as compound J.

13) I respectfully disagree with this allegation. The fact that oxidative stress may play a significant role in the pathogenesis of MS is not unique to MS. Indeed, oxidative stress may play a significant role in several other CNS diseases, such as Alzheimer's and Parkinson's disease. And like MS, the track record of successfully treating these diseases with antioxidants has been scanty if not poor. This poor track record for CNS diseases in general further supports the non-obviousness of my invention directed to treating MS in particular.

I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willfully false statements are punishable by fine or imprisonment under 18 U.S.C. Section 1001 and that any such statement may jeopardize the validity of the subject application or any patent issued thereon.

Daphne Atlas

12 October 2010

Dr. Daphne Atlas — Date